REMARKS/ARGUMENTS

This is responsive to the issues raised in the Official Action of January 23, 2009, a Final Rejection.

New claims 36-45 are presented above based upon previous claims 1-14 and 31-35, respectively.

These new claims have been drafted with the examiner's comments on pages 2-3 of the most recent Official Action in mind, namely that despite a 1:1 ratio of the two components involved, there is concern that the claims could read on amounts to be so small as to not reach therapeutic levels. Indeed, this was the subject of an informal discussion with the examiner on January 16, 2009 when the examiner suggested that all of the independent claims should be amended to specify an effective amount.

With the examiner's earlier comments in mind applicants have amended their claims and, for convenience, presented them in the form of new claims, in each claim specifying an effective amount of the acetyl L-carnitine and the propionyl L-carnitine in addition to the weight ratio of 1:1. In addition, claims 41-45 also include weight ranges for each of these two components based on weight per kilogram body weight of the subject being treated. These weight ranges are based upon the original description of the invention, for instance, page 2, last paragraph of the description as well as original claim 5. Accordingly, the new claims presented above are based upon disclosed subject matter and are supported by the description of the invention.

It is counsel's understanding that because the claims were interpreted to be potentially not of therapeutic level of one or both components and therefore "synergism" was not demonstrated, at least with respect to the claims then under consideration, the prior art rejections of record were continued. Clearly that is no longer the case, in that applicants have fully demonstrated synergistic properties well within therapeutic amounts as the claims clearly state. Withdrawal of the rejections based upon prior art is appropriate considering the amendments made to the claims and, perhaps more importantly, the evidence already of record in this application.

For completeness the following remarks are included:

The Official Action of January 23, 2009 includes two rejections based upon prior art; they are directed to claims 12-14 as allegedly being "obvious" over Calvani while claims 31 and 32 are rejected over the same reference in combination with an article by Walker.

The application as filed includes comparative evidence showing synergistic results, and to require therapeutic amounts as well as in claims 46-50 a weight range for each of the two essential components. This is in addition to the ratio of the two components involved as used in the comparisons to demonstrate synergism, that is a 1:1 ratio.

Claims 36-38 refer to a method for protecting kidney from dysfunction caused by lithium by administering acetyl L-carnitine in combination with propionyl L-carnitine. Calvani et al. U.S. 5,955,424 describe the administration of L-carnitine **or** alkanoyl L-carnitine for inhibiting nephrotoxicity due to immunosuppressant drugs. Calvani et al. do not discloses a combination comprising the two compounds in a single formulation and, more importantly Calvani et al. do **not refer to lithium** as a nephrotoxic agent.

The experimental results reported in from page 7 - last 5 lines to page 9 – table 3, of the specification of the subject application, show that the combination of acetyl L-carnitine with propionyl L-carnitine has a **synergic effect**. From the data in table 3 it can be easily understood that the post-lithium-infusion time is **halved** by the combination in comparison to the two components alone.

The results could not be predicted merely by looking at the disclosure of Calvani et al. In fact, the skilled person could not expect the behavior of the combination and the presence of a synergic effect by looking at the effects of the single components.

The evidence of unexpected results as shown by the data provided in Table 3 of the originally filed specification provide sufficient basis for demonstration of a surprising and synergistic effect provided by L-carnitine in combination with propionyl L-carnitine.

Walker represents the background art on damage caused by lithium on the kidney. The applicant was aware at the time of filing of the nephrotoxic activity of lithium, as mentioned in page 8 lines 1-2, and knew that lithium causes tubular necrosis. Walker et al. do not add any additional information to those given by Calvani et al.

For the above reasons it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration and allowance are solicited. Should the examiner require further information, please contact the undersigned.

Respectfully submitted,

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